K073046

510(k) Summary

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Glenda C Marsh
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FEB 25 2008

Date Prepared October 26, 2007

New Device Name Trade Name: Ethicon Endo Surgery® Articulating Needle Knife
Common or Usual Name: Electrosurgical Needle Electrodes
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

Predicate Devices KSEA Monopolar Coagulating Needle Electrode (K972497)
Colorado MicroDissection Needle (K000348)
Boston Scientific RX Needle Knife (K970053)

Device Description The Ethicon Endo Surgery® (EES) Articulating Needle Knife is an endoscopic instrument intended for cutting, dissecting and cauterizing tissue via high-frequency electrical current waveform. The device consists of a flexible wire cable and needle knife electrode, which can be extended, rotated, articulated, and retracted from the flexible outer shaft using a three-finger actuator. When connected to an electrosurgical generator and activated, the Needle Knife delivers a monopolar electrical current to the surgical site. This device passes through endoscopes having a 3.2 mm or larger working channels. This device is supplied sterile for single-patient use.

Indications for Use The Articulating Needle Knife is a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. The Articulating Needle Knife is not intended for use in the central nervous system or in the central circulatory system.

Technological Characteristics The EES device has similar technologic characteristics to the predicate devices in that it contains a metal electrode tip that is used to deliver monopolar energy to the surgical site. In all devices the electrode tip is in the shape of a needle. All devices are designed to be connected to electrosurgical generators, and utilize RF monopolar energy for operation.

The EES device is similar to the Boston Scientific RX Needle Knife in that it consists of an elongated flexible wire shaft and a handle. These devices allow for the manipulation

of the needle knife via the handle of the device. In addition, the EES device features rotation and articulation of the end-effector to provide the clinician with improved tissue targeting capability.

Performance Data. Bench testing was performed to demonstrate that the EES device performs as intended. The device materials have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1. The device was tested to demonstrate compliance with the following standards:

- AAMI / ANSI HF 18:2001, *Electrosurgical Devices*
- IEC/EN 60601-2-2:2000, *Medical electrical Equipment — Part 2-2: Particular requirements for the safety of high frequency surgical equipment*
- IEC/EN 60601-2-18:1996, *Medical electrical equipment — Part 2: Particular requirements for safety — Section 2.18 Specification for endoscopic equipment*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2008

Ethicon End-Surgery, Inc.
% Ms. Glenda C. Marsh
Project Manager, QS/RA
4545 Creek Road
Cincinnati, Ohio 45242

Re: K073046
Trade/Device Name: Ethicon Endo Surgery® Articulating Needle Knife
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: II
Product Code: GEI
Dated: February 11, 2008
Received: February 12, 2008

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K073046**

Device Name: **Ethicon Endo Surgery® Articulating Needle Knife**

Indications for Use:

The Articulating Needle Knife is a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. The Articulating Needle Knife is not intended for use in the central nervous system or in the central circulatory system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K073046